HAMMERTUBE SYSTEM

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION.

This booklet is designed to assist in using the HammerTube™ System. It is not a reference for surgical techniques.

CAUTION
Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

GENERAL DESCRIPTION
The HammerTube™ System is comprised of a sterile, PEEK (Polyetheretherketone) fixation device and stainless steel K-wires. The PEEK implants are offered in diameters of Ø2.75mm and Ø3.50mm, with 0° and 10° angled options. The K-wires range in diameters from Ø1.1mm to Ø1.8mm. The system instruments include inserters, drills, planers, trephine removal tool, and a threaded extractor.

IMPLANT MATERIALS
The dowels are manufactured from PEEK per ASTM F2026 with a titanium plasma spray that conforms to ASTM F1580. The K-wires are manufactured from Stainless Steel per ASTM F138. The instrumentation is manufactured from medical grade stainless steels and plastics.

INDICATIONS FOR USE
The HammerTube™ System is indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the device.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the device. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System.

CONTRAINDICATIONS
The HammerTube™ System is contraindicated for use in patients with an active or suspected infection; in patients who are physiologically or psychologically inadequate; in patients previously sensitized to titanium; in patients with insufficient quantity or quality of bone to permit stabilization of the bony segments; in patients with high level of activity; or where there is a possibility for conservative treatment.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments and K-wires are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the HammerTube™ System.**
- **Do not re-sterilize the HammerTube™ System implants.**

MR SAFETY INFORMATION
The HammerTube™ System has been evaluated for safety and compatibility in the MR environment. The HammerTube™ System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the HammerTube™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MAINTAINING DEVICE EFFECTIVENESS
- The surgeon should have specific training, experience, and thorough familiarity with the use of fixation devices.
- The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
- The HammerTube™ implants are not intended to endure excessive abnormal functional stresses.
- The HammerTube™ implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique HammerTube™ system instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION
STERILE PRODUCT
Paragon 28® HammerTube™ implants are provided sterile using gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use implants after expiration date. Packages for implants should be intact upon receipt.

Implants in sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, DO NOT USE THE IMPLANT. Contact the manufacturer for further instructions. The implants should be opened using aseptic technique. The implant should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.

All implants should be stored in a clean, dry environment.

NON-STERILE PRODUCT
Product that is presented in a tray is provided non-sterile. All non-sterile implants and instruments should be cleaned using established hospital methods before sterilization and introduction into the sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Pragon 28®, Inc. ***Instrument Reprocessing Instructions for Reusable Instruments*** (P20-CLN-0001). This is also available by calling (855) 786-2828.

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

INSTRUCTIONS FOR USE
The HammerTube™ System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques. Refer to the HammerTube™ System Surgical Technique (P40-STG-1001) for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28®, Inc. by phone, (855) 786-2828.

IMPLANT REMOVAL
- Instrumentation can be provided for implant removal.
- Removal instructions are provided in the HammerTube™ System Surgical Technique (P40-STG-1001).

PRODUCT COMPLAINTS
The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact company for product inquiries and surgical techniques, or to report adverse incidence.

Paragon 28®, Inc.
[illegible]erness Ct. E., Suite 280
Englewood, CO 80112 USA
(855) 786-2828

EC REP
Emergo Group
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

CE 0086

Symbol Explanations

EC REP	Authorized EU Representative			Manufacturer
LOT	Lot Number		NON STERILE	Non-sterile
REF	Item Number			Do Not Reuse
	Consult IFU		R_x Only	For prescription use only
	Keep Dry			Caution, consult accompanying documents
	Use By Date		STERILE R	Sterilized using irradiation
STERILIZE	Do Not Re-sterilize			Do not use if package is damaged

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INDICATIONS FOR USE
The HammerTube™ System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures.

The cannulated and solid HammerTube™ implants may be used with [illegible] other additional device. The cannulated implants may be used with K-wires for delivery of implants or for the temporary stabilization of nearby joints, such as the metatarsophlanageal joint.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System.

CONTRAINDICATIONS
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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

Paragon 28®, Inc.
4B Inverness Ct. E.,
Suite 280
Englewood, CO 80112
USA
(855) 786-2828

EC REP
Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Emergo Australia
Level 20, Tower II
Darling Park
201 Sussex St.
Sydney NSW 2000
Australia

CE 0086 **Symbol Explanations**

EC REP	**Authorized EU Representative**			**Manufacturer**
LOT	**Lot Number**		NON STERILE	**Non-sterile**
REF	**Item Number**			**Do Not Reuse**
	Consult IFU		**R_x Only**	**For prescription use only**
	Keep Dry			**Caution, consult accompanying documents**
	Use By Date		STERILE R	**Sterilized using irradiation**
	Do Not Re-sterilize			**Do not use if package is damaged**